AUG - 7 2001

K011423

Applicant:	Incisive, LLC 3095 Richmond Parkway Suite 213 Richmond, CA 94806
Contact Person:	Michael Yessik, CEO Tel: 510-669-9401 Fax: 510-669-9398
Date Prepared:	May 8, 2001
Device Trade Name:	InPulse Dental Laser
Common Name:	Nd:YAG Pulsed Laser
Classification Name:	Instrument, Surgical, Powered, Laser 79-GEX
Legally Marketed Predicate Device:	Dentica Dental Laser American Dental PulseMaster SunLase 800P Dental Laser
Description of the Incisive InPulse Dental Laser	The laser head consists of a flashlamp-pulsed Nd:YAG rod in an optical resonant cavity. The energy and the width of each laser pulse are determined by the size and shape of the current pulse through the flashlamp. The output energy of each laser pulse is measured by the internal energy monitor. The laser beam emitted from the laser head is coupled into a fiber-optic cable at the fiber port. The laser aperture is at the distal tip of the fiber. The operator controls the laser through the push-button control panel. A microcontroller handles all of the logic required to set the energy levels, pulse widths, and repetition rates for the laser output, monitors the output pulses to assure proper output energy, monitors all of the interlocks and sensors, and checks for proper operation of the switches, power supplies, and cooling system.
Summary Basis of Equivalence:	The InPulse is a free-running Nd:YAG laser based on the same technology as the predicate devices. It has been re-designed primarily to provide the same performance in a smaller size and at lower cost. The laser beam, delivered to the tissue via a standard optical fiber, has identical physical characteristics and tissue effects as the predicate devices. The indications for use and intended uses are also identical. There are no new safety issues.

Intended use:

The following are the oropharangeal indications for use for which the device will be marketed:

Abscess Incision and Drainage
Aphthous Ulcers Treatment
Biopsies, Excisional and Incisional
Crown Lengthening
Exposure Of Unerupted / Partially Erupted Teeth
Fibroma□ Removal
Frenectomy
Frenotomy
Gingival Incision and Excision
Gingivectomy
Gingivoplasty
Hemostatis
Implant Recovery
Lesion (tumor) removal
Leukoplakia
Operculectomy
Oral Papillectomy
Pulpotomy
Pulpotomy as adjunct to root canal therapy
Removal of filling material such as gutta percha or resin as adjunct treatment during root canal re-treatment
Selective Ablation of Enamel (First Degree) Caries Removal
Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility
Tissue Retraction For Impressions
Vestibuloplasty

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2001

Mr. Michael Yessik
Chief Executive Officer
Incisive, LLC
3095 Richmond Parkway
Suite 213
Richmond, California 94806

Re: K011423
Trade/Device Name: InPulse Dental Laser
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: May 8, 2001
Received: May 9, 2001

Dear Mr. Yessick:

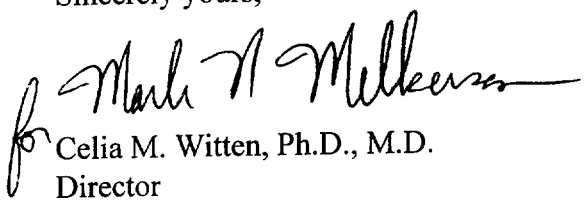
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 011423

8. Intended Uses of the Device:

The ***InPulse Nd:YAG Dental Laser System*** is to provide the ability to perform intraoral soft tissue dental, general, oral maxillo-facial and cosmetic surgery. The InPulse is intended for ablating, incising, excising, vaporization and coagulation of soft tissues using a contact fiber optic delivery system. The device will be used in the following areas: general and cosmetic dentistry, otolaryngology, dermatology & plastic surgery, The following are the oropharangeal indications for use for which the device will be marketed:—

- Abscess Incision and Drainage
- Aphthous Ulcers Treatment
- Biopsies, Excisional and Incisional
- Crown Lengthening
- Exposure Of Unerupted / Partially Erupted Teeth
- Fibroma□ Removal
- Frenectomy
- Frenotomy
- Gingival Incision and Excision
- Gingivectomy
- Gingivoplasty
- Hemostatis
- Implant Recovery
- Lesion (tumor) removal
- Leukoplakia
- Operculectomy
- Oral Papillectomy
- Pulpotomy
- Pulpotomy as adjunct to root canal therapy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal re-treatment
- Selective Ablation of Enamel (First Degree) Caries Removal
- Sulcular Debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility
- Tissue Retraction For Impressions
- Vestibuloplasty

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011423